CLINICAL STUDY: EVALUATING THE USABILITY AND CLINICAL PERFORMANCE OF THE NUKUTE COLLARE SYSTEM

CLINICAL EVALUATION TEAM

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CLINICAL PERFORMANCE

Clinical performance data was collected under ethical committee permission at the Oulu University Hospital, department of Clinical Neurophysiology, and Pirkanmaa Hospital District Clinical Neurophysiological sleep department, during 12/2020 – 03/2021.

The study was conducted as comparative measurement, patients wore both Nukute Collare and respiratory polygraphy golden standard reference device or polysomnography golden standard reference device.

Data was collected from 45 Finnish adults with or without suspected sleep apnea: 64.4% male and 35.6% female.

ABBREVIATIONS

Sensitivity: Sensitivity measures how often device correctly generates a positive result for people who have the condition that's being tested for (also known as the "true positive" rate). A test that's highly sensitive will flag almost everyone who has the disease and not generate many false-negative results.

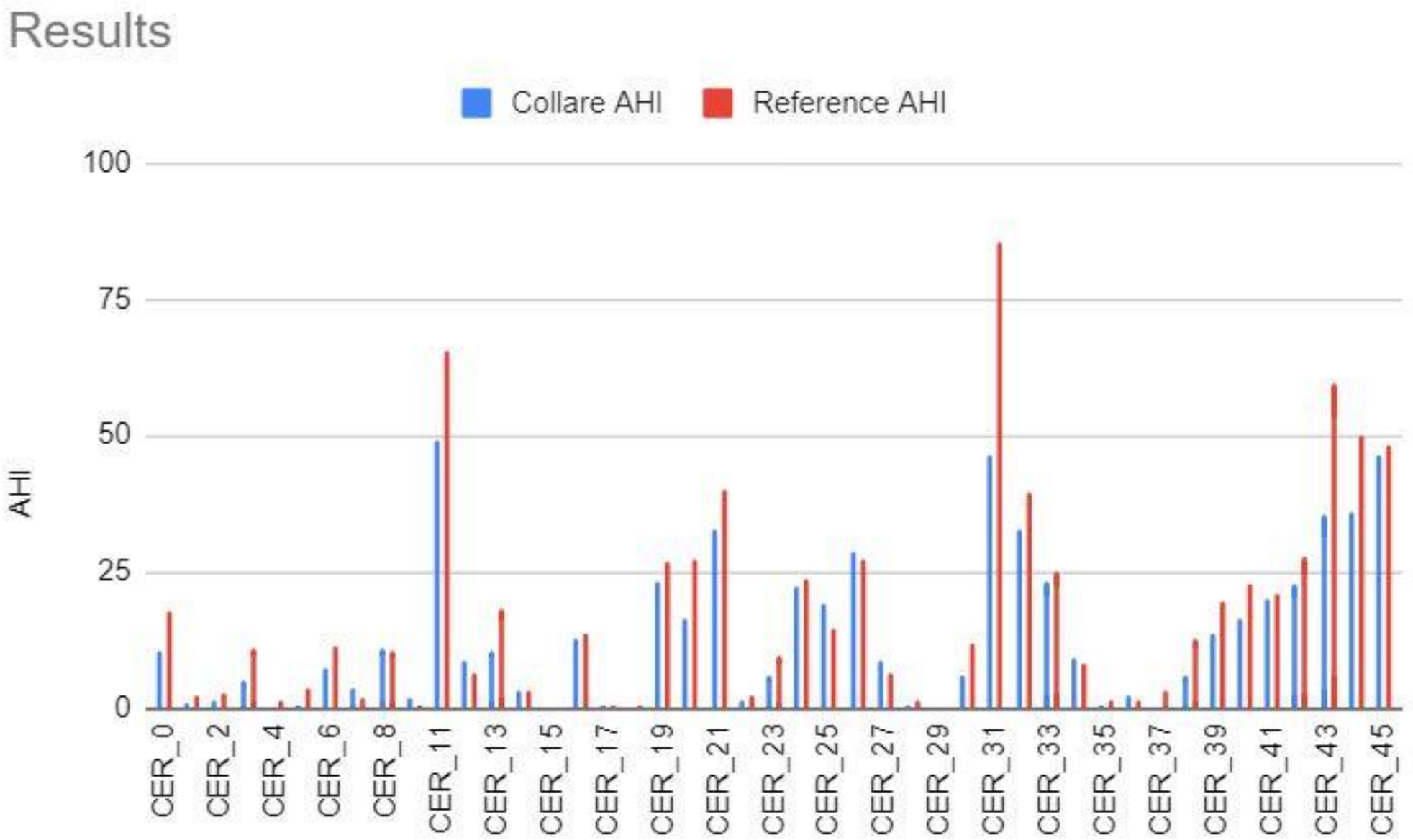
Specificity: Specificity measures a device ability to correctly generate a negative result for people who don't have the condition that's being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out almost everyone who doesn't have the disease and won't generate many false-positive results.

PPV= Positive Predictive value = the probability that subjects with a positive screening test truly have the disease

NPV= Negative Predictive value= the probability that subjects with a negative screening test truly don't have the disease

AHI COMPARISON

With scoring of hypopneas using a ≥ 3% desaturation event as threshold, the mean ± standard deviation of AHI/REI was **17.52 ± 19.58** events/h on Nox, and **13.39 ± 14.08** events/h on Collare.



NUKUTE

COLLARE VS GOLDEN STANDARD REFERENCE DEVICES, SEVERITY CLASSIFICATION ANALYSIS

	No OSA	Mild	Moderate	Severe
Golden standard reference devices	16	11	11	7
Collare	16	13	9	7

Severity classification results of golden standard reference devices and Collare

Golden standard reference device and Collare analysis results Confusion matrix

Collare vs. Reference devices	No OSA	Mild	Moderate	Severe
No OSA	16	0	0	0
Mild	0	10	3	0
Moderate	0	1	8	0
Severe	0	0	0	7

SENSITIVITY AND SPECIFICITY

Comparison based on a threshold of:

- AHI/REI ≥ **5** events/h, Collare had 100% sensitivity, 100% specificity, 100% positive predictive value, and 100% negative predictive value compared to AASM golden standard reference devices.
- AHI/REI ≥ **15** events/h, Collare had 83% sensitivity, 96% specificity, positive predictive value 94%, and negative predictive value 90%.
- AHI/REI ≥ **30** events/h, Collare had 100% sensitivity, 100% specificity, positive predictive value 100%, and negative predictive value 100%.
- By comparing class matches, Collare had 91% sensitivity, 97% specificity, 91% positive predictive value, and 97% negative predictive value

AHI/REI, events/h	Sensitivity	Specificity	PPV	NPV
≥ **5**	1.00	1.00	1.00	1.00
≥ **15**	0.83	0.96	0.94	0.90
≥ **30**	1.00	1.00	1.00	1.00
Class match	0.91	0.97	0.91	0.97

Sensitivity, specificity, and positive (PPV) and negative (NPV) predictive value for different cutoffs of manually scored AHI/REI from AASM golden standard reference devices versus Collare.

SUMMARY

A total of 296 hours of audio data was recorded during the 45 measurements approved for Clinical Investigation. 3978 AHI events, from which 1240 were apnea and 2738 were hypopnea events, were detected from the data.

The good agreement can be seen also in the binary classification cases using varying thresholds of AHI/REI. Using the threshold AHI/REI ≥ 5 events/h, balanced accuracy is 1.0. With AHI/REI ≥ 15 events/h, balanced accuracy is 0.90 and with AHI/REI ≥ 30 it is 1.0.

Nukute Collare system records the breathing sound and SpO2 data of the patient during sleep and visualizes the data. Sleep apnea specialist can use the visualized data for detecting and scoring sleep apnea. Automatic algorithms helps to speed up the sleep apnea professionals' scoring of measurement data by automatically estimating events. In case of interrupted measurement or invalid data detected by the specialist, Collare allows the patient to measure multiple nights in a row in home environment without complex setups.

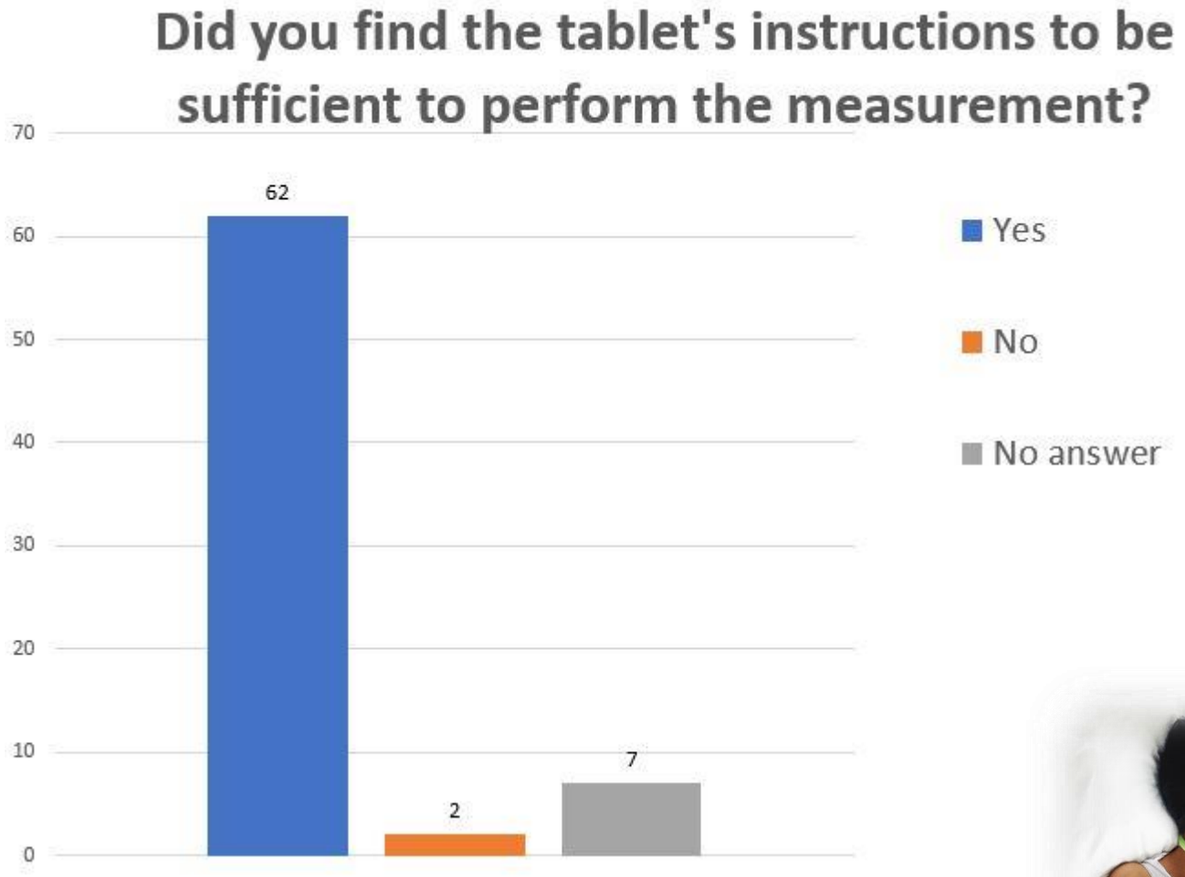
USABILITY

Usability data was collected by using questionnaire form from the patients involved with the investigation.
There were 14 questions to answer. Question 14 was free form to which written feedback could be submitted.
Data was collected from 71 patients.

INSTRUCTIONS

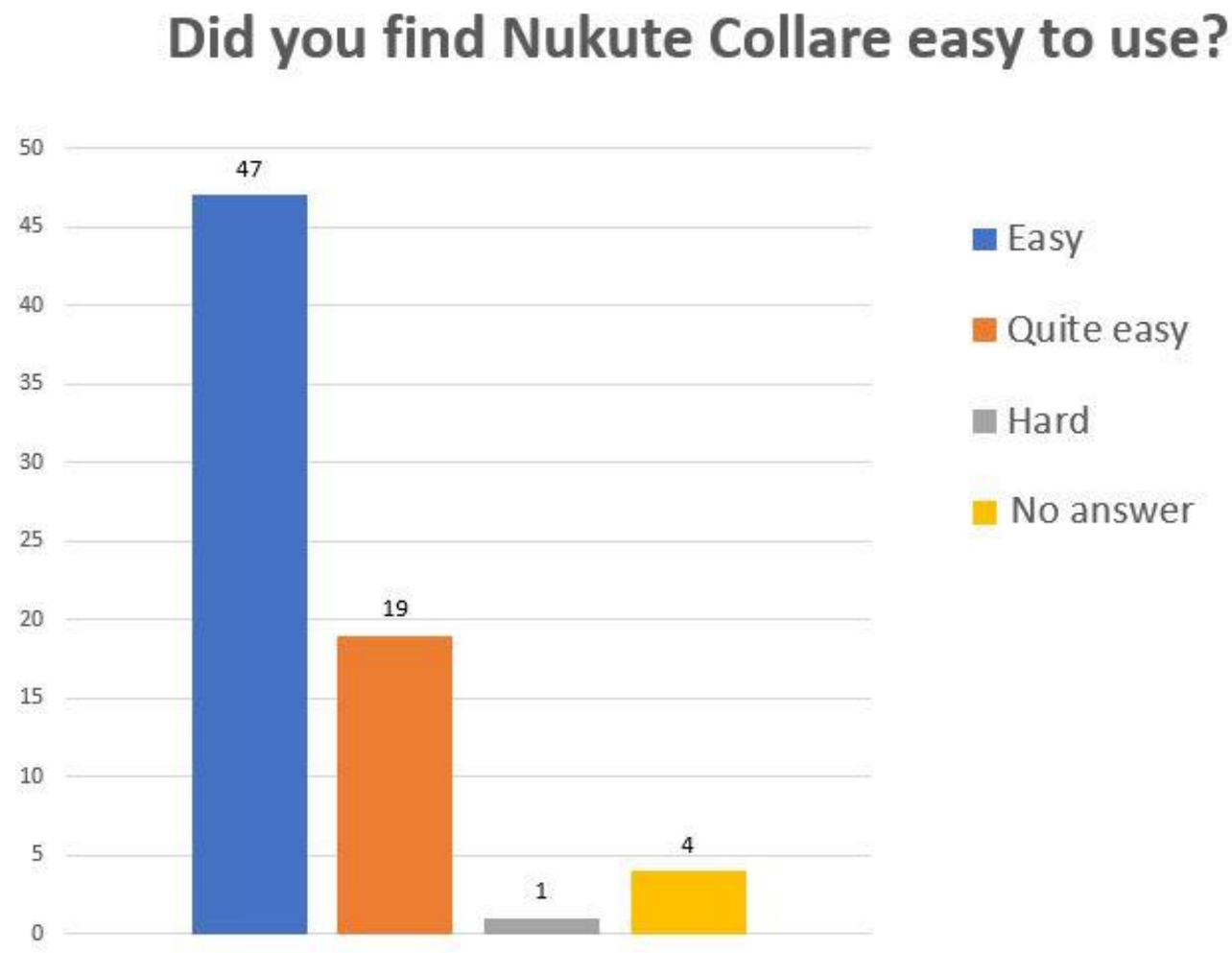
Nukute Collare interactive user instructions are visualized on the tablet as patient begins the measurement. A printed quick guide is also provided inside the carrying case.

Most of the patients felt that the instructions were sufficient for the patients to perform the actual measurement.



EVALUATION OF INTUITIVITY AND EASE-OF-USE

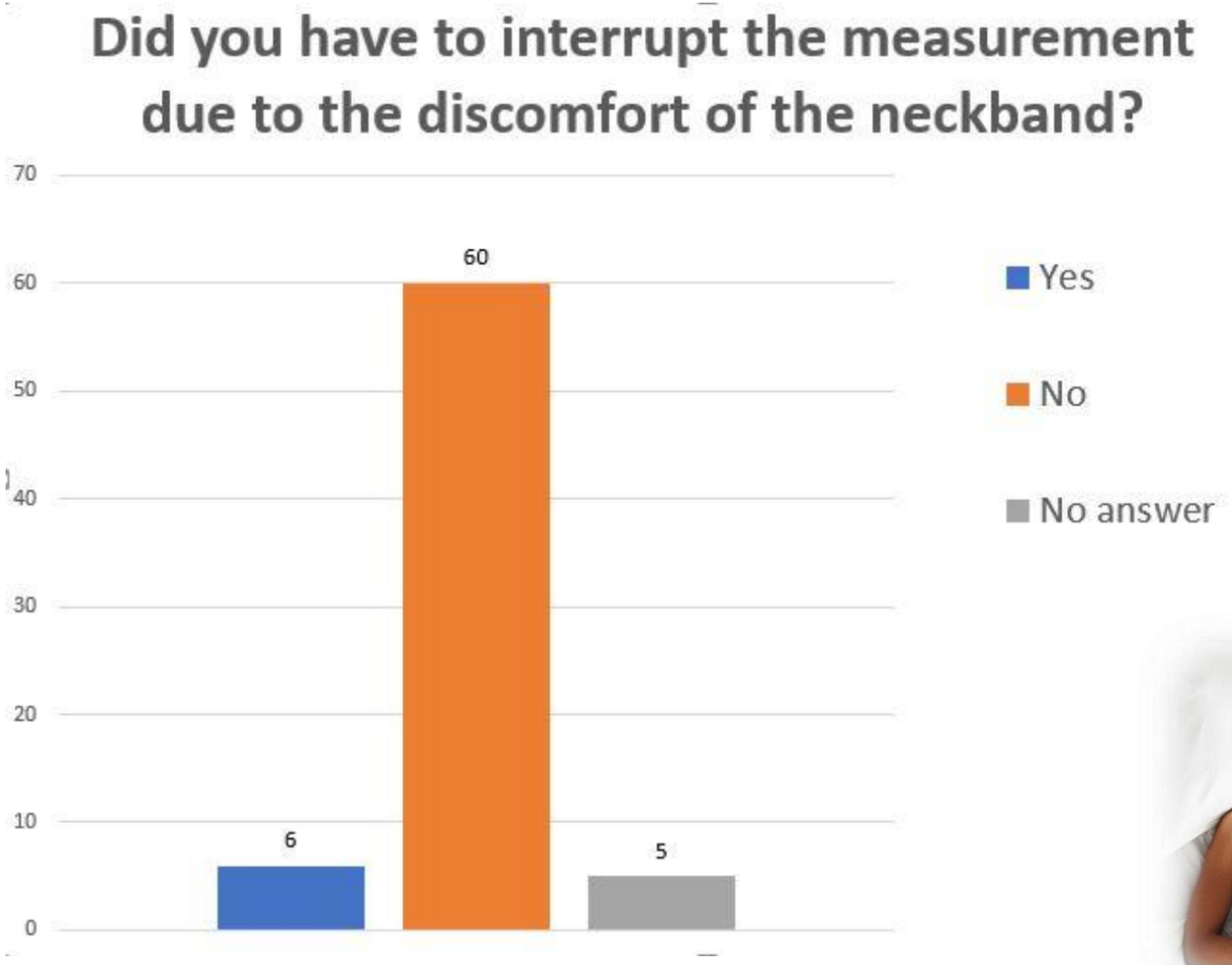
Based on the answers, it can be concluded that Nukute Collare was easy to use.



COMFORTABILITY - USAGE DURING THE NIGHT

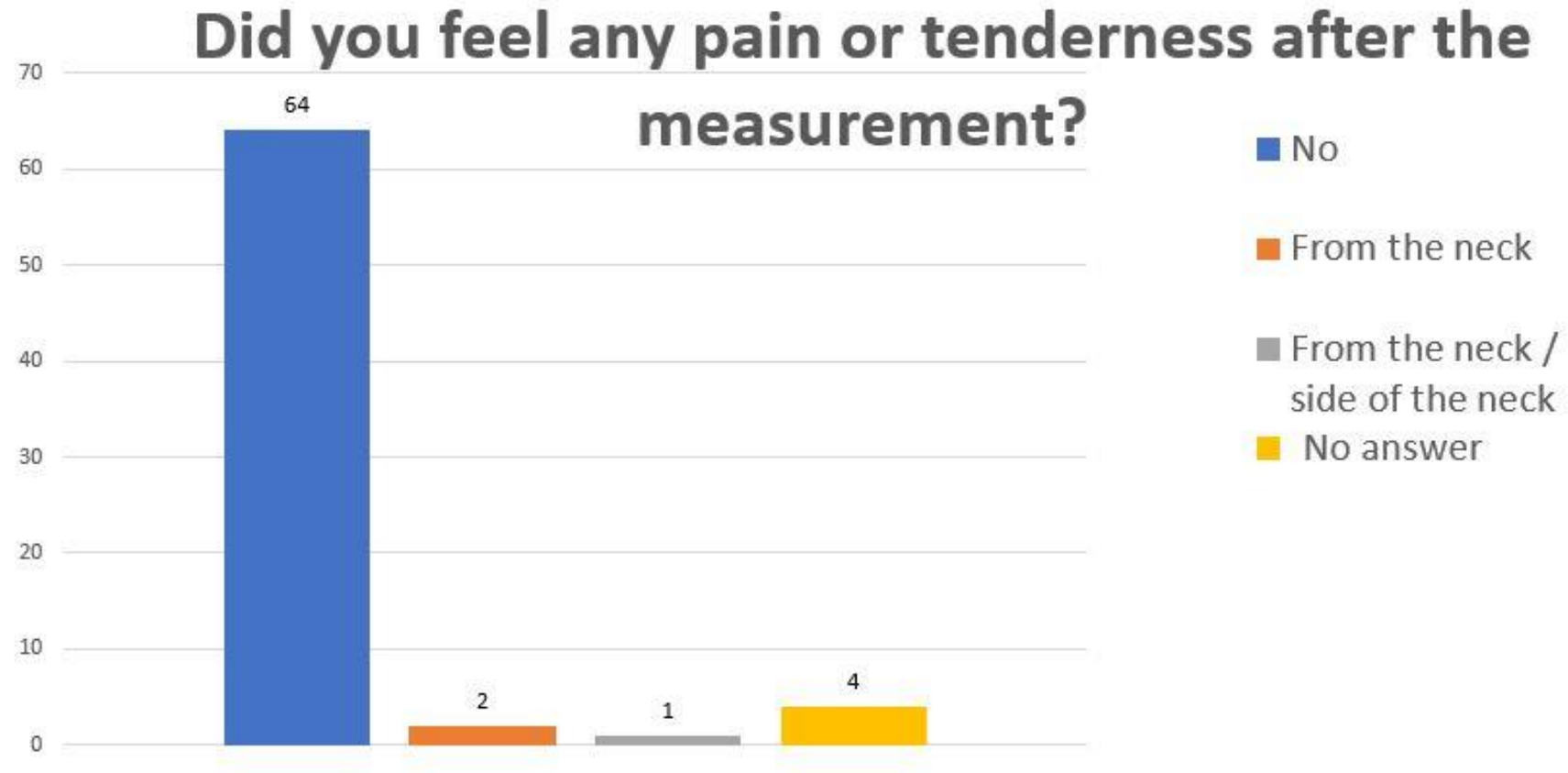
Based on the results from the questions concerning the usage during the night it can be summarised that the test patients slept quite well with the Nukute Collare system.

60 patients out of 71 answered that they did not have to interrupt the measurement because of the Collare.



COMFORTABILITY – AFTER THE NIGHT

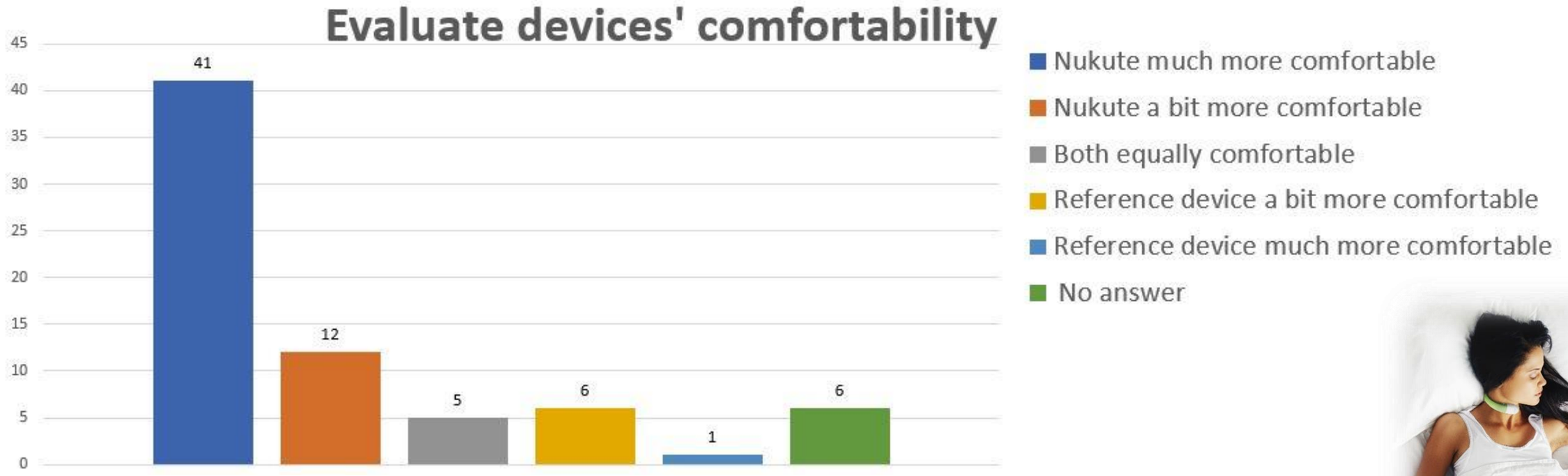
Based on the answers it was rare that Nukute Collare caused any pain or tenderness after the measurement.



USER EXPERIENCE

During the usability evaluation patients wore both the Nukute Collare and AASM Golden Standard reference device.

Patients evaluated the comfort of the devices after the measurement. 41 patients out of 71 considered the Nukute Collare system to be much more comfortable than the AASM Golden Standard reference device.



USER EXPERIENCE

During the usability evaluation patients wore both the Nukute Collare and AASM Golden Standard reference device.

Patients evaluated the comfort of the devices after the measurement and 60 patients would wear the Nukute Collare system again.